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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

TAYLOR, JANELLE

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 09/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/761,569

Applicant(s)

DAVIS ET AL.

Examiner

Janell Cleveland Taylor

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 33-43, 51, 52 and 56-74 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 33-43, 51, 52 and 56-74 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Detailed Action*.

**DETAILED ACTION**

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claim 60, drawn to the method of claim 51, wherein the reagent enhances MKK activity, classified in class 514, subclass 2.
  - II. Claim 61, drawn to the method of claim 51, wherein the reagent decreases MKK activity, classified in class 514, subclass 2.
  - III. Claim 65, wherein the reagent is an antibody that specifically binds to a polypeptide having the amino acid sequence of SEQ ID NO: 2, classified in class 424, subclass 130.1.
  - IV. Claim 65, wherein the reagent is an antibody that specifically binds to a polypeptide having the amino acid sequence of SEQ ID NO: 4, classified in class 424, subclass 130.1.
  - V. Claim 65, wherein the reagent is an antibody that specifically binds to a polypeptide having the amino acid sequence of SEQ ID NO: 6, classified in class 424, subclass 130.1.
  - VI. Claim 65, wherein the reagent is an antibody that specifically binds to a polypeptide having the amino acid sequence of SEQ ID NO: 8, classified in class 424, subclass 130.1.
  - VII. Claim 65, wherein the reagent is an antibody that specifically binds to a polypeptide having the amino acid sequence of SEQ ID NO: 10, classified in class 424, subclass 130.1.

- VIII. Claims 66-67, drawn to the method of claim 51, wherein the reagent is a polypeptide having the amino acid sequence of SEQ ID NO: 2, classified in class 530, subclass 350.
- IX. Claims 66-67, drawn to the method of claim 51, wherein the reagent is a polypeptide having the amino acid sequence of SEQ ID NO: 4, classified in class 530, subclass 350.
- X. Claims 66-67, drawn to the method of claim 51, wherein the reagent is a polypeptide having the amino acid sequence of SEQ ID NO: 6, classified in class 530, subclass 350.
- XI. Claims 66-67, drawn to the method of claim 51, wherein the reagent is a polypeptide having the amino acid sequence of SEQ ID NO: 8, classified in class 530, subclass 350.
- XII. Claims 66-67, drawn to the method of claim 51, wherein the reagent is a polypeptide having the amino acid sequence of SEQ ID NO: 10, classified in class 530, subclass 350.
- XIII. Claim 68, drawn to the reagent being an antisense nucleic acid or a ribozyme, classified in class 435, subclass 6.
- XIV. Claim 69, drawn to the reagent modulating MKK3 activity, classified in class 514, subclass 2.
- XV. Claim 70, drawn to the reagent modulation MKK4 alpha activity, classified in class 514, subclass 2.

- XVI. Claim 71, drawn to the reagent modulating MKK4 beta activity, classified in class 514, subclass 2.
- XVII. Claim 72, drawn to the reagent modulating MKK4 gamma activity, classified in class 514, subclass 2.
- XVIII. Claim 73, drawn to the reagent modulating MKK6 activity, classified in class 514, subclass 2.

The inventions are distinct, each from the other because of the following reasons:

1. Claims 51-52, 57-59, 62-64, and 74 link(s) inventions 1-23. The restriction requirement among the linked inventions is subject to the non-allowance of the linking claim(s), 51-52, 57-59, 62-64, and 74. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application, except for the restriction required for the SEQ ID NOS (see below.) Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

2. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have exact opposite effects, as one enhances activity while the other decreases activity.

1. Inventions 3-7 and 8-12 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to proteins and antibodies. Antibodies have different functions than proteins and nucleic acids, i.e., the antibody attaches to the protein, often disabling it from functioning, and the protein is useful for carrying out various cellular functions. The protein and the nucleic acid are capable of functioning in the cell without the antibody being present, and can be used by the practitioner to create enzymes, or for diagnostic testing, or in the case of nucleic acids, to form probes or primers. Furthermore, the peptide is capable of functioning without the antibody being present in the cell, in fact, the protein usually cannot function when the antibody is present.

2. Inventions III-XII and XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a nucleic acid and a protein, which have different functions, i.e., the nucleic acid codes for protein and the

protein is used for various purposes in the cell, in the instant case as an MKK modulator. The nucleic acid is capable of functioning to code for a peptide without the peptide being present, and can be used by the practitioner to create probes, primers, and for diagnostic purposes without the presence of the peptide. Furthermore, the peptide is capable of functioning without the nucleic acid being present in the cell.

3. Inventions XIV-XVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to different MKKs, each having a different effect, different function, and different structure.

***Sequence Election Requirement Applicable to All Groups***

In addition, some of the claims detailed above read on patentably distinct Groups drawn to multiple SEQ ID Numbers. The sequences are patentably distinct because they are unrelated sequences, and a further restriction is applied to the sequences. For an elected Group drawn to amino acid sequences, the Applicants must further elect a single amino acid sequence. For an elected Group drawn to nucleotide sequences, the Applicants are permitted to elect up to 10 nucleic acid sequences (See MPEP 803.04).

MPEP 803.04 states:

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. Nevertheless, to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided sua sponte to

partially waive the requirements of 37 CFR 1.141 et seq. and permit a reasonable number of such nucleotide sequences to be claimed in a single application. See Examination of Patent Applications Containing Nucleotide Sequences, 1192 O.G. 68 (November 19, 1996).

It has been determined that normally ten sequences constitute a reasonable number for examination purposes. Accordingly, in most cases, up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction. In addition to the specifically selected sequences, those sequences which are patentably indistinct from the selected sequences will also be examined. Furthermore, nucleotide sequences encoding the same protein are not considered to be independent and distinct inventions and will continue to be examined together.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

5. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, etc., restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).



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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janell Taylor Cleveland whose telephone number is 703-305-0273. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on 703-308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Janell Taylor Cleveland  
Examiner  
Art Unit 1634

September 9, 2002

  
W. Gary Jones  
Supervisory Patent Examiner  
Technology Center 1600